

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS	)	
CORPORATION,	)	
	)	
Plaintiff	)	
	)	
v.	)	C.A. No. _____
	)	
LIQUIDIA TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	
	)	

**COMPLAINT**

Plaintiff United Therapeutics Corporation (“UTC”), by its undersigned attorneys, for its Complaint against Defendant Liquidia Technologies, Inc. (“Liquidia”), alleges as follows:

**NATURE OF THE ACTION**

1. This is a Hatch-Waxman action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, §§ 100, *et seq.*, and an action for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq.*, involving United States Patent No. 10,716,793 (“the ’793 patent”) (attached as Exhibit A hereto). The ’793 patent is listed in the FDA’s *Approved Drug Products with Therapeutic Equivalents* publication (also known as the “Orange Book”).

2. UTC currently markets TYVASO<sup>®</sup> (treprostinil) inhalation solution, which was first approved by the FDA in 2009, and TYVASO DPI<sup>®</sup> (treprostinil) inhalation powder, which was approved by the FDA in 2022. TYVASO DPI<sup>®</sup> is the first marketed dry powder formulation of treprostinil in the United States. Liquidia seeks approval to market YUTREPIA<sup>®</sup>, a second dry powder formulation of treprostinil.

3. This action arises out of Liquidia’s submission of New Drug Application (“NDA”) No. 213005 and an amendment thereto, filed under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act and pursuant to 21 U.S.C. § 355(b)(2) (“Liquidia’s § 505(b)(2) Application” or “§ 505(b)(2) Application”), submitted to the U.S. Food and Drug Administration (“FDA”) and seeking approval to engage in the commercial manufacture, use, or sale of YUTREPIA® (treprostinil) for inhalation (“Proposed § 505(b)(2) Product”) before expiration of the ’793 patent.

4. After a bench trial in *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:20-cv-755-RGA-JLH (“prior District of Delaware action”) involving Liquidia’s initial § 505(b)(2) application, the United States District Court for the District of Delaware entered judgment finding that YUTREPIA® infringes valid claims of the ’793 patent. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:20-cv-755-RGA-JLH, D.I. 436 at ¶ 3 (D. Del. Sept. 9, 2022). This action, arising out of submission of Liquidia’s § 505(b)(2) Application, alleges that YUTREPIA® infringes claims of the ’793 patent.

### **THE PARTIES**

5. UTC is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 10040 Spring Street, Silver Spring, Maryland 20910. UTC is a biotechnology company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions. UTC continues to research and develop treatments for cardiovascular and pulmonary diseases, pediatric cancers, and other orphan diseases.

6. Upon information and belief, Liquidia is a corporation organized and existing under the laws of the State of Delaware, with a registered office at 251 Little Falls Drive, Wilmington,

Delaware 19808, and a principal place of business at 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560.

### **JURISDICTION AND VENUE**

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

8. This Court has personal jurisdiction over Liquidia because, among other things, Liquidia is a corporation organized and existing under the laws of the State of Delaware with a registered agent in the State of Delaware. Liquidia has publicly stated its preparation for commercialization and intent to engage in commercializing Liquidia's Proposed § 505(b)(2) Product throughout the United States as soon as possible and without any limitation. Upon information and belief, Liquidia will manufacture, market, store, distribute, sell and/or offer to sell Liquidia's Proposed § 505(b)(2) Product throughout the United States, including in the State of Delaware, and will derive substantial revenue therefrom.

9. Further, upon information and belief, Liquidia has committed, aided, abetted, contributed to, or participated in the commission of a tortious act of patent infringement by submitting and maintaining its § 505(b)(2) Application that has led to foreseeable harm and injury to UTC, and will imminently commit, induce, aid, abet, contribute to, or participate in the commission of a tortious act of patent infringement by selling its Proposed § 505(b)(2) Product in the United States, including in the State of Delaware, which will lead to foreseeable harm and injury to UTC. Upon information and belief, upon approval of Liquidia's § 505(b)(2) Application, Liquidia will place its Proposed § 505(b)(2) Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased

and used by consumers in the State of Delaware. Upon information and belief, Liquidia has made, and continues to make, substantial preparation to engage in the commercial manufacture, use, distribution, offer to sell, or sale of Liquidia's Proposed § 505(b)(2) Product.

10. This Court also has personal jurisdiction over Liquidia because it has availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of organization for itself and/or subsidiaries and consenting to jurisdiction by participating in lawsuits and/or asserting counterclaims and/or filing complaints in lawsuits that are filed in this Court. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:20-cv-755-RGA-JLH (D. Del.); *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:21-mc-377-RGA-JLH (D. Del.); *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:21-mc-325-RGA (D. Del.).

### **BACKGROUND**

11. Pulmonary arterial hypertension (PAH) is a rare disease affecting the pulmonary vasculature and involving high pressure in the pulmonary arteries, which increases strain on the right ventricle of the heart, thereby leading to heart failure and death.

12. In 2009, FDA approved UTC NDA No. 022387 for TYVASO® (treprostinil) inhalation solution for the treatment of PAH. FDA granted UTC a period of new indication exclusivity which runs through March 31, 2024.

13. The '793 patent, entitled "Treprostinil Administration by Inhalation," was duly and legally issued by the United States Patent and Trademark Office on July 21, 2020, and is scheduled to expire on May 14, 2027. The named inventors are Horst Olschewski, Robert Roscigno, Lewis J. Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel.

14. UTC is the lawful owner of the '793 patent by assignment of all right, title, and interest in and to the '793 patent, including the right to bring infringement suits thereon.

### **ACTS GIVING RISE TO THIS ACTION**

15. Liquidia notified UTC by letter dated July 24, 2023 ("Liquidia's July 2023 Notice Letter") that it had submitted an amendment to NDA No. 213005 to FDA seeking approval to engage in the commercial manufacture, use and/or sale of Liquidia's Proposed § 505(b)(2) Product, prior to the expiration of the '793 patent.

16. Liquidia's amendment to NDA No. 213005 describes a modification to the original application and submission of the amendment required a "Paragraph IV" certification. Liquidia's amendment to NDA No. 213005 provides the basis for a new infringement cause of action and warrants an automatic 30-month stay of approval.<sup>1</sup>

17. Liquidia's July 2023 Notice Letter included a statement pursuant to 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c)(6) purporting to recite Liquidia's factual and legal basis for its opinion that the '793 patent is invalid, unenforceable, and/or that certain claims are not, and will not, be infringed by the commercial manufacture, use or sale of Liquidia's Proposed § 505(b)(2) Product. The Notice Letter does not dispute infringement of claims 1, 4, or 6-8 of the '793 patent and includes only a conclusory statement that the claims of the '793 patent are invalid because of a decision by the Patent Trial and Appeal Board in an *Inter Partes* Review (IPR)

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<sup>1</sup> See Notification Pursuant to § 505(b)(3)(B) of the Federal Food, Drug, & Cosmetic Act (21 U.S.C. § 355(b)(3)(B)(i)) and 21 C.F.R. § 314.52) from Liquidia Techs., Inc., to United Therapeutics Corp., The Corp. Trust, Inc., and Goodwin Procter LLP (Jul. 24, 2023) (attached as Exhibit B hereto); *FORM 10-Q*, U.S. SEC. & EXCHANGE COMM'N at 53 (Aug. 10, 2023), <https://www.liquidia.com/static-files/8d6b2bd8-aa0d-459a-ab4e-a5cbe415d205> ("United Therapeutics may bring a new Hatch-Waxman suit for patent infringement, which may trigger a new mandatory 30-month delay . . . in approval of the 505(b)(2) NDA application").

proceeding. That IPR proceeding is currently on appeal, and UTC's opening brief includes at least three grounds justifying reversal.

18. Upon information and belief, as of the date of Liquidia's July 2023 Notice Letter, Liquidia was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c)(6).

19. UTC commenced this action before the expiration of 45 days from the date it received Liquidia's July 2023 Notice Letter.

20. Because UTC brought suit within 45 days of receiving notice of Liquidia's "Paragraph IV" certification, this suit will trigger an automatic statutory 30-month stay of approval by the FDA of Liquidia's § 505(b)(2) Application to allow the parties time to adjudicate the merits of the infringement action before Liquidia launches its Proposed § 505(b)(2) Product. 21 U.S.C. § 355(j)(5)(B)(iii).

21. Upon information and belief, Liquidia intends to commercially manufacture, distribute, sell, offer for sale, and/or import Liquidia's Proposed § 505(b)(2) Product upon, or in anticipation of, FDA approval.

22. Upon information and belief, Liquidia will and/or has manufactured, imported, prepared, acquired, and/or stockpiled commercial batches of treprostinil sodium API and Liquidia's Proposed § 505(b)(2) Product for release, use, and/or sale upon FDA approval.

23. Liquidia's manufacturing, importing, preparing, acquiring, and/or stockpiling is not solely for uses reasonably related to the development and submission of information for approval of Liquidia's § 505(b)(2) Application. Therefore, it does not qualify for the safe harbor in 35 U.S.C. § 271(e)(1).

24. For example, as early as November 8, 2021, Liquidia’s CEO, Damian deGoa, announced that Liquidia “will now focus our efforts on pre-commercial launch activities and the growing market opportunity for YUTREPIA in PAH and potential new indications.”<sup>2</sup> On March 16, 2023, in Liquidia’s Full Year 2022 Financial Results and Corporate Update, Liquidia states that “the increase of \$9.3 million or 40% [in general and administrative expenses] was primarily due to a \$4.2 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA . . . .”<sup>3</sup> On August 10, 2023, in Liquidia’s Second Quarter 2023 Financial Results and Corporate Update, Liquidia states that “there was a \$2.2 million increase in expenses related to our YUTREPIA program driven by higher manufacturing and supply costs,” and that “[t]he increase of \$2.3 million or 33% [in general and administrative expenses] was primarily due to a \$1.3 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA . . . .”<sup>4</sup>

25. Liquidia has coordinated with respect to the manufacture, import, storage, and distribution of Liquidia’s Proposed § 505(b)(2) Product, and will continue to do so, in substantial and meaningful preparation for immediate launch of Liquidia’s Proposed § 505(b)(2) Product upon FDA approval.

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<sup>2</sup> *FDA Grants Tentative Approval for Liquidia’s YUTREPIA™ (Treprostinil) Inhalation Powder*, LIQUIDIA CORP. (Nov. 8, 2021), <https://liquidia.com/news-releases/news-release-details/fda-grants-tentative-approval-liquidias-yutrepia™-treprostinil>.

<sup>3</sup> *Liquidia Corporation Reports Full Year 2022 Financial Results and Provides Corporate Update*, LIQUIDIA CORP. (Mar. 16, 2023) <https://www.globenewswire.com/news-release/2023/03/16/2628438/0/en/Liquidia-Corporation-Reports-Full-Year-2022-Financial-Results-and-Provides-Corporate-Update.html>.

<sup>4</sup> *Liquidia Corporation Reports Second Quarter 2023 Financial Results and Provides Corporate Update*, LIQUIDIA CORP. (Aug. 10, 2023) <https://www.liquidia.com/news-releases/news-release-details/liquidia-corporation-reports-second-quarter-2023-financial>.

**COUNT I: INFRINGEMENT OF  
U.S. PATENT NO. 10,716,793 UNDER 35 U.S.C. § 271(e)**

26. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

27. Upon information and belief, Liquidia's Proposed § 505(b)(2) Product is covered by one or more claims of the '793 patent.

28. Upon information and belief, Liquidia has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, storage, distribution, and/or importation of Liquidia's Proposed § 505(b)(2) Product, prior to the expiration of the '793 patent.

29. Liquidia's submission and maintenance of its § 505(b)(2) Application for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Liquidia's Proposed § 505(b)(2) Product prior to the expiration of the '793 patent is an act of infringement of the '793 patent under 35 U.S.C. § 271(e)(2).

30. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Liquidia's Proposed § 505(b)(2) Product, if approved, will infringe one or more claims of the '793 patent.

31. Upon information and belief, Liquidia has acted without a reasonable basis for believing that it would not be liable for infringement of the '793 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

32. Upon information and belief, Liquidia has acted and/or is continuing to act despite an objectively high likelihood that its actions constituted infringement of a valid patent, and knew or should have known of that objectively high risk at least as early as the August 31, 2022 Trial Opinion in *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:20-cv-755-RGA-JLH, D.I. 433 (D. Del. Aug. 31, 2022). Thus, upon information and belief, Liquidia's infringement of

the '793 patent has been, and continues to be, knowing, intentional and willful, thereby entitling UTC to enhanced damages and reasonable attorneys' fees and costs under 35 U.S.C. § 284.

33. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '793 patent is not enjoined by this Court. Liquidia's acts of infringement of the '793 patent have caused and will continue to cause UTC immediate and irreparable harm unless such infringing activities by Liquidia, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation, or privity with them, and their successors and assigns are enjoined by this Court pursuant to 35 U.S.C. § 283 and/or 35 U.S.C. § 271(e)(4)(B). UTC does not have an adequate remedy at law.

**COUNT II: INFRINGEMENT OF  
U.S. PATENT NO. 10,716,793 UNDER 35 U.S.C. §§ 271(a)-(c)**

34. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

35. Liquidia's § 505(b)(2) Application and its intention to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Liquidia's Proposed § 505(b)(2) Product upon receiving FDA approval of Liquidia's § 505(b)(2) Application prior to the expiration of the '793 patent creates an actual and justiciable controversy with respect to infringement of the '793 patent.

36. Upon information and belief, Liquidia has indicated its intent to engage, and its past engagement, in the commercial manufacture, use, offer for sale, sale, marketing, storage, distribution, and/or importation of Liquidia's Proposed § 505(b)(2) Product prior to the expiration of the '793 patent.

37. Upon information and belief, Liquidia's Proposed § 505(b)(2) Product is covered by one or more claims of the '793 patent.

38. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Liquidia's Proposed § 505(b)(2) Product, if approved, will infringe one or more claims of the '793 patent.

39. Upon information and belief, upon FDA approval of Liquidia's § 505(b)(2) Application, Liquidia's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Liquidia's Proposed § 505(b)(2) Product will directly infringe one or more claims of the '793 patent, and will indirectly infringe by actively inducing and/or contributing to infringement by others, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

40. Upon information and belief, the use of Liquidia's Proposed § 505(b)(2) Product, in accordance with the YUTREPIA® label, if approved, will directly infringe, either literally or under the doctrine of equivalents, at least one claim of the '793 patent under 35 U.S.C. § 271(a).

41. Upon information and belief, Liquidia will induce others to infringe one or more claims of the '793 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to the manufacturer of Liquidia's Proposed § 505(b)(2) Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its manufacture or administration thereof constitutes direct infringement of one or more claims of the '793 patent. Upon information and belief, Liquidia's aiding and abetting includes Liquidia's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Liquidia's § 505(b)(2) Application.

42. Liquidia has actual knowledge of the '793 patent and will actively induce direct infringement of at least one claim of the '793 patent under 35 U.S.C. § 271(b) if Liquidia's § 505(b)(2) Application is approved and Liquidia's Proposed § 505(b)(2) Product is marketed, sold, stored, distributed, and/or imported.

43. Upon information and belief, Liquidia will also infringe one or more claims of the '793 patent under 35 U.S.C. § 271(c) in that it will make, use, sell, offer to sell, and/or import Liquidia's Proposed § 505(b)(2) Product and/or the API thereof, which it knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '793 patent.

44. To the extent Liquidia will and/or has manufactured, imported, prepared, acquired, and/or stockpiled Liquidia's Proposed § 505(b)(2) Product in the United States for sale in the United States in anticipation of FDA approval, such activities infringe or will infringe the '793 patent.

45. Upon information and belief, Liquidia was and is aware of the existence of the '793 patent, and acted without a reasonable basis for believing that it would not be liable for infringement of the '793 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

46. Upon information and belief, Liquidia has acted and/or is continuing to act despite an objectively high likelihood that its actions constituted infringement of a valid patent, and knew or should have known of that objectively high risk at least as early as the August 31, 2022 Trial Opinion in *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:20-cv-755-RGA-JLH, D.I. 433 (D. Del. Aug. 31, 2022). Thus, upon information and belief, Liquidia's infringement of the '793 patent has been, and continues to be, knowing, intentional and willful, thereby entitling UTC to enhanced damages and reasonable attorneys' fees and costs under 35 U.S.C. § 284.

47. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '793 patent is not enjoined by this Court. Liquidia's acts of infringement of the '793 patent have caused and will continue to cause UTC immediate and irreparable harm unless such infringing activities by Liquidia, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation, or privity with them, and their successors and assigns are enjoined by this Court pursuant to 35 U.S.C. § 283. UTC does not have an adequate remedy at law.

### **PRAYER FOR RELIEF**

WHEREFORE, UTC requests the following relief:

1. A declaration that the '793 patent is infringed by Liquidia;
2. A judgment or declaration that:
  - a. Liquidia has infringed at least one claim of the '793 patent under 35 U.S.C. § 271(e)(2) by submitting, maintaining and/or supporting the submission or maintenance of Liquidia's § 505(b)(2) Application; and
  - b. Liquidia will infringe, either literally or under the doctrine of equivalents, actively induce infringement of, and/or contribute to the infringement by others of the '793 patent under 35 U.S.C. §§ 271(a)-(c), (f) or (g), by making, using, selling, offering for sale, or importing into the United States Liquidia's Proposed § 505(b)(2) Product, or any product or compound that infringes one or more claims of the '793 patent, prior to the expiration date of the '793 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;

3. A judgment ordering that the effective date of any FDA approval of Liquidia's NDA No. 213005 and an amendment thereto, permitting Liquidia to commercially manufacture, make, use, offer to sell, sell, market, or import into the United States Liquidia's Proposed § 505(b)(2) Product, be not earlier than the expiration date of the '793 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;
4. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 preliminarily and permanently enjoining Liquidia, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation, or privity with them, and their successors and assigns, from infringing, contributorily infringing, or inducing others to infringe the '793 patent, including engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of Liquidia's § 505(b)(2) Application and/or any applicable DMF(s) until the expiration of the '793 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;
5. A judgment awarding UTC damages or other monetary relief, pursuant to 35 U.S.C. § 271(e)(4)(C), for any engagement by Liquidia in commercial manufacture, use, sale, offer to sell and/or importation into the United States of any product that is the subject of Liquidia's § 505(b)(2) Application that infringes one or more claims of the '793 patent, prior to the expiration date of the '793 patent, including any

extension(s) and/or additional period(s) of exclusivity to which UTC is or may become entitled;

6. A judgment in favor of UTC and against Liquidia determining that Liquidia has willfully and deliberately committed acts of patent infringement, and awarding UTC enhanced damages in light of Liquidia's willful infringement pursuant to 35 U.S.C. § 284, including reasonable attorneys' fees and costs;
7. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding UTC its attorneys' fees;
8. An award of costs and expenses in this action to UTC; and
9. Such further and other relief as this Court may deem just and proper.

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September 5, 2023

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